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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,385	04/13/2006	Marcus A. Horwitz	51326-00019	8534

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EXAMINER	
NAVARRO, ALBERT MARK	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/595,385	HORWITZ ET AL.	
	Examiner	Art Unit	
	Mark Navarro	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-30,32 and 41-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-30,32 and 41-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/11/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment filed November 11, 2008 has been received and entered. Claims 1-26, 31 and 33-40 have been cancelled, and new claims 44-46 have been added. Accordingly, claims 27-30, 32, and 41-46 are pending in the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. The rejection of claims 27-32 and 41-43 under 35 U.S.C. 102(e) as being anticipated by Horwitz et al is withdrawn in view of Applicants Declaration to change inventorship under 37 CFR 1.132 showing that Marcus Horwitz and Gunter Harth are the sole inventors of the remaining claims, thereby demonstrating that the patent to Horwitz is not "by another."

2. The rejection of claims 27-30 and 41-43 under 35 U.S.C. 102(e) as being

anticipated by Orme et al is maintained.

Additionally, this rejection is applied to newly added claims 44-46.

Applicants are asserting that Orme does ***not disclose*** that the Ag85A is a 30 kDa protein, rather a 32 kDa protein. Applicants conclude that Orme et al does not teach each and every limitation of the instant claims.

Applicants arguments have been fully considered but are not found to be fully persuasive.

Applicants assert that Orme does ***not disclose*** that the Ag85A is a 30 kDa protein, rather a 32 kDa protein. However, Applicants are respectfully directed to the summary section of Orme et al, specifically summary paragraph number 14, which sets forth that "Horwitz et al, 1995, claimed that Ag85 protein protected guinea pigs against aerosol TB. This study was said by the authors to demonstrate that ***immunization with the Mtb 30 kDa major secretory protein (Ag85A)***, alone or in combination with other abundant extracellular Mtb protein induced strong cell-mediated immune responses and substantial protective immunity against aerosol challenge with virulent Mtb bacilli in the highly susceptible guinea pig model of pulmonary tuberculosis." (Emphasis added). Furthermore, determination of a molecular weight is usually an approximation at best, what one of ordinary skill in the art may call a band 32 kDa, another looking at the exact same band on the exact same gel, may call the same band 30 kDa. In other words, Applicants have not shown that the M. tuberculosis major extracellular protein identified solely by a molecular weight of 30 kDa, excludes Ag85A. Given that the claims do not recite any particular structure (e.g., SEQ ID NO), the recitation of major extracellular

protein Mtb 30 kDa is deemed to fully encompass the Mtb Ag85A major extracellular protein, which was also reported to have a molecular weight of 30 kDa by those of skill in the art.

The claims are directed to a prime boost vaccine strategy for protecting a mammal against infection by a pathogen of the genus Mycobacterium comprising administering a first priming immunogenic composition to a vaccinee wherein said first priming immunogenic composition is a BCG; administering a second boosting immunogenic composition, after the passage of a period of time, to said vaccinee optionally in the presence of an adjuvant, wherein said second boosting immunogenic composition comprises at least one purified Mycobacteria major extracellular protein selected from the group consisting of Mycobacterium tuberculosis (Mtb) 23.5 kDa, Mtb 30 kDa, Mycobacterium bovis (MB) 30 kDa, MB 32 kDa, Mycobacterium leprae (ML) 23.5 kDa, ML 30 kDa and ML 32 kDa; and wherein a protective immune response against said pathogen of the genus Mycobacterium is produced in said vaccinee.

Orme et al (US Patent Number 7,288,261) disclose of vaccine compositions for boosting immunity to mycobacteria when administered in mide life in a subject who has been vaccinated with BCG. Orme et al further disclose that a preferred protein for boosting is Ag85A, a secreted Mycobacteria major extracellular protein having a molecular weight of 30 kDa. (See abstract and claims).

For reasons of record, as well as the reasons set forth above, this rejection is

maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. The rejection of claims 27-30, 32 and 41-43 under 35 U.S.C. 103(a) as being unpatentable over Horwitz et al in view of Orme et al is maintained.

Additionally, this rejection is applied to newly added claims 44-46.

Applicants are again asserting that Orme et al only teach of a protective immune

response with Mtb Ag85A having a molecular weight of 32 kDa, not 30 kDa. Applicants further assert that in order to rely on the "obvious to try" standard, there must be a finite number of identified, predictable solutions. *KSR Intl Co. v. Teleflex.,* 127 S. Ct. 1727.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants again assert that Orme et al only teach of a protective immune response with Mtb Ag85A having a molecular weight of 32 kDa, not 30 kDa. However, this argument has been fully addressed above in paragraph number 2.

Finally, Applicants further assert that in order to rely on the "obvious to try" standard, there must be a finite number of identified, predictable solutions. However, Applicants are respectfully directed to the success achieved by Orme et al. Orme et al specifically set forth that when selecting individuals who had received BCG early in life and then administering a boost of a major extracellular Mtb protein (described to have a molecular weight of 30 kDa as set forth above) a noted rise in the level of protection was achieved. (See abstract and claims). Consequently, no obvious to try standard is necessary, the prior art actually demonstrates success.

The claims are directed to a prime boost vaccine strategy for protecting a mammal against infection by a pathogen of the genus Mycobacterium comprising administering a first priming immunogenic composition to a vaccinee wherein said first priming immunogenic composition is a BCG; administering a second boosting immunogenic composition, after the passage of a period of time, to said vaccinee

optionally in the presence of an adjuvant, wherein said second boosting immunogenic composition comprises at least one purified Mycobacteria major extracellular protein selected from the group consisting of Mycobacterium tuberculosis (Mtb) 23.5 kDa, Mtb 30 kDa, Mycobacterium bovis (MB) 30 kDa, MB 32 kDa, Mycobacterium leprae (ML) 23.5 kDa, ML 30 kDa and ML 32 kDa; and wherein a protective immune response against said pathogen of the genus Mycobacterium is produced in said vaccinee.

Horwitz et al (PNAS Vol. 97, No. 25, pp 13853-13858, December 5, 2000) teach that recombinant BCG vaccines which express the Mycobacterium tuberculosis 30 kDa major secretory protein induced greater protective immunity against tuberculosis than conventional BCG vaccines in a highly susceptible animal model. (See abstract). Horwitz et al further teach that “immune response to the 30 kDa protein may be a critical factor in protective immunity to TB." (See page 13858).

Horwitz et al do not teach of administering a second boosting immunogenic composition which is a purified Mycobacteria major extracellular protein.

Orme et al (US Patent Number 7,288,261) teach of vaccine compositions for boosting immunity to mycobacteria specifically for individuals who were previously vaccinated with BCG. (See abstract). Orme et al reports that adults vaccinated with BCG as young children become relatively unprotected. (See summary).

Given that Horwitz et al teach of the superiority of a recombinant BCG vaccine which expressed the Mycobacterium tuberculosis 30 kDa major secretory protein, and that 2) Orme et al teach of vaccine compositions for boosting the immune response to Mycobacteria, and specifically teach of the 30 kDa major secretory protein for

administration to individuals vaccinated with BCG, it would have been prima facie obvious to have incorporated the step of administering a 30 kDa major secretory protein as taught by Orme et al with the method of vaccination as taught by Horwitz et al. One would have been motivated to add the booster step in view of the teaching by Orme et al that adults vaccinated with BCG as young children become relatively unprotected.

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Navarro/
Primary Examiner, Art Unit 1645
January 26, 2009